Bureau of Insurance

A Report to the Joint Standing Committee on Insurance and Financial Services of the 121st Maine Legislature

Review and Evaluation of
LD 213, an Act to Assist Maine's Infertile Citizens

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I. Executive Summary

The Joint Standing Committee on Insurance and Financial Services of the 121st Maine Legislature directed the Bureau of Insurance to review LD 213, an Act to Assist Maine's Infertile Citizens. The review was conducted using the requirements stipulated under 24-A M.R.S.A., §2752 as amended by Public Law 2001, Chapter 258. This review was a collaborative effort of Mercer Risk, Finance & Insurance Consulting, Inc. (Mercer) and the Maine Bureau of Insurance (Bureau).

LD 213 would amend sections of Maine Law pertaining to health policies and HMOs. As written, the bill would not apply to certificates issued in Maine under a group policy issued in another state. The bill would require:

- All group health plans, including health maintenance organizations, that provide for coverage for pregnancy-related benefits to provide coverage for the diagnosis and treatment of infertility, including, but not limited to, in vitro fertilization, embryo transfer, artificial inseminations, gamete intrafallopian tube transfer, zygote intrafallopian tube transfer and low tubal ovum transfer.
- All group health plans, including health maintenance organizations that provide prescription drug coverage shall not include restrictions on prescription medications or a restriction or limitation on the number of procedures used for infertility diagnosis or treatment.

The bill contains the following features to control costs:

- In order to be eligible for benefits, the female partner must be 21 years of age or older and under 45 years of age.
- The policy may require that the covered individual has been unable to attain or sustain a successful pregnancy through reasonable, less costly medically appropriate infertility treatments for which coverage is available under the policy.
- Benefits are limited to six intrauterine inseminations with ovarian simulation unless the individual already has one child in which case benefits are limited to three.
- The policy may limit the covered individual to a maximum of 4 completed oocyte retrievals, except that if the individual has a living child, then the policy may limit coverage to 2 completed oocyte retrievals.

The Committee on Insurance and Financial Services also requested that the impact of infertility coverage on the cost of other health care services be studied, for example whether the costs of health care services and insurance claims would be higher for babies born as a result of infertility treatment.

Health insurance carriers surveyed have provided suggestions regarding the wording and benefits of the proposed mandate. These suggestions can be found on page 21 of the report.

Insurers generally do not provide infertility coverage in their standard plans but most make it available as an option to large employers. Typically, these options have limits on the amount of benefits available.

We estimate there are about 18,000 Maine women of childbearing age that have or will receive infertility services sometime in their life. This represents about 1.4% of Maine's entire population. In any given year, about 4,000 Maine women, or 0.3% of the population, will have an infertility appointment. Of course the incidence rate of women seeking assistance for infertility could be understated because most health insurance policies do not provide coverage for infertility, and those that do, generally have limitations. Please note that not all infertility is associated with females; however infertility treatments are almost 100% associated with females. Therefore, incidence rates are expressed in the number of women seeking treatment, which includes those situations involving male infertility as well.

The cost of treatment for infertility varies by the type of treatment and can become quite expensive. Successful treatments typically contain indirect costs in the form of more high risk pregnancies and a significant increase in multiple birth incidence. A comprehensive infertility mandate can reduce the incidence of multiple births by removing financial hardships of failed Assisted Reproductive Therapy (ART) cycles. However, the bill as currently written, incorporates limits on lifetime attempts for ART, and may actually encourage the transfer of multiple embryos to increase the chance of pregnancies if a woman has few cycles remaining in the benefit. A high number of transferred embryos increases the incidence of multiple births.

We estimate the total cost of the proposed mandate, including both direct and indirect costs, to be $3.53 per member per month (PMPM) or 1.4% of premium. The direct costs, the costs of the infertility treatment itself, after a reduction for services that may already be provided under a different diagnosis, will range from $0.69 PMPM to $1.22 PMPM, or 0.3% to 0.5% of premium.

The indirect costs for this benefit are significant. Maternity costs for women who become pregnant using ART are significantly higher than normal. Although births from ART account for less than 1% of all live births, they now account for about a third of all twin births and more than 40% of triplets and higher. These indirect costs range from $1.55 PMPM to $2.30 PMPM, or 0.6% to 0.9% of premium. There is an additional indirect cost in that there is evidence that the frequency of birth defects is significantly higher for babies conceived using ART than for babies conceived naturally. Because of the difficulties in estimating the increased lifetime costs associated with birth defects, we have not explicitly included this in our estimate of indirect costs. Instead, we have reflected this additional cost by using the high end of the range determined for other direct and indirect costs.

Self-funded plans would not have to comply with LD 213 and therefore would not experience an increase in costs.

II. Background

The Joint Standing Committee on Insurance and Financial Services of the 121st Maine Legislature directed the Bureau of Insurance to review LD 213, an Act to Assist Maine's Infertile Citizens. The review was conducted using the requirements stipulated under 24-A M.R.S.A., §2752 as amended by Public Law 2001, Chapter 258. This review was a collaborative effort of Mercer Risk, Finance & Insurance Consulting, Inc. (Mercer) and the Maine Bureau of Insurance (Bureau).

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There is a range of treatments for infertility that would be covered under this bill. While "low tubal ovum transfer" is mentioned in the proposed bill, we understand this procedure is no longer performed. A glossary of terms is in Appendix E. The treatment of infertility is complex. Diagnosing infertility requires the following steps[1]:

1. Evaluate the couple simultaneously
2. Utilize a "step" approach
3. Develop a one-two month diagnostic plan.

Initial Tests

- History/physical examination
- Semen analysis
- Ovulation evaluation
  - basal body temperature
  - LH kits
- Luteal progeteron
- Postcoital test
- Ultrasonography
- Hysterosalphingogram (HSG)
- Endometrial biopsy

Secondary Tests

- Hormonal screening
- Diagnostic laparoscopy
- Hysteroscopy
- Sperm antibodies

After the evaluation, there are five basic methodologies used to treat infertility.

- Hormonal therapy
  There are several drugs used to treat infertility. Care must be taken not to over stimulate or produce too many eggs, which can result in Ovarian Hyperstimulation Syndrome or multiple births.
- Surgical procedures and microsurgery
  Surgical procedures are often used in conjunction with other techniques for the comprehensive treatment of infertility.

[1] William M. Mercer, *Infertility as a Covered Benefit*, 1997

- Artificial insemination
  This is a commonly used technique, cost effective and can be done in the doctor's office.
- Assisted Reproductive Therapy (ART)
  The most common ARTs are: in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT) and Zygote intrafallopian transfer (ZIFT). Hormones are used in conjunction with ART. Most couples do not require this kind of treatment.
- Micromanipulation techniques
  Used when the male has a severely restricted sperm count or the motility of the sperm is dramatically reduced. Often used with IVF.

The current insurance law does not have specific requirements for infertility benefits to be covered. Insurers generally do not provide this coverage in their standard plans but most make it available as an option to large employers. The Bureau issued Bulletin 206 in 1992 to clarify terms as they apply to insurance coverage for procedures and services related to infertility. For those policies that cover treatment of infertility the Bulletin provided a definition of infertility unless an alternative definition was provided in the contract.

At the present time, Medicare and Medicaid do not cover infertility services.

Currently, three other states, Massachusetts, Illinois and Rhode Island, have adopted laws requiring health insurance companies that offer policies with maternity benefits to also provide infertility benefits. New Jersey has enacted a similar mandate, but only for groups of 51 or more employees and limits treatment to persons age 45 and younger. Three states, California, Connecticut and Texas, require carriers to offer infertility riders. Several states, Arkansas, Colorado, Delaware, Georgia, Maryland, Minnesota, Montana, Missouri, New Mexico, New York, and West Virginia provide limited infertility benefits.[2] These limited benefits range from counseling to limited ART and for groups with more than fifty employees.

Virginia, Pennsylvania and Washington, considered mandating infertility treatments but rejected them because of costs.[3]

III. Social Impact

[2] 2003 National Association of Insurance Commissioners (NAIC) Compendium of State Laws on Insurance Topics
[3] Pennsylvania Health Care Cost Containment Council, www.phc4.orf/reports/mandates/1183/Executove.htm and Washington State Department of Health, health Systems Quality Assurance, Infertility Mandated Benefits Sunrise

A. Social Impact of Mandating the Benefit

1. The extent to which the treatment or service is utilized by a significant portion of the population.

A commonly accepted definition of infertility is twelve months or more of unprotected intercourse without pregnancy. Using this definition, the proposed benefit would be used by a small portion of the population.

There is a range of estimates regarding the incidence of infertility among women. In its 2000 report on ART, the Centers for Disease Control and Prevention (CDC) indicated that in 1995 about 2% of women of reproductive age had had an infertility-related medical appointment within the previous year. The report further states that 13% of women of childbearing age had received infertility services at one time in their life.[4] An article in the New England Journal of Medicine estimates that the number of infertile women of child bearing age is about 4 million. This study defined eligibility for infertility treatment to be limited to women 25 to 45 years of age. This, too, equates to an infertility incidence rate of about 13% of eligible women.[5] Translating these statistics to Maine's population means that about 18,000 women of childbearing age will need infertility assistance in their lifetime and slightly less than 4,000 women will seek assistance in any one year. (Please note that not all infertility is associated with females; however, infertility treatments are almost 100% associated with females. Therefore, incidence rates are expressed in the number of women seeking treatment, which includes those situations involving male infertility as well.)

The National Center for Health Statistics study found that infertility affects 10% of the female population aged 15 to 44 years of age.[6] Using this definition, there are about 26,000 infertile Maine women.
These sources indicate there are between 18,000 and 26,000 women of childbearing age in Maine who are infertile, or between 1.4% to 2.1% of Maine's

Review, January 2001
[4] 2000 National Report, Assisted Reproductive Technology Success Rates, Nation Summary and Fertility Clinic Reports, Center for Disease Control and Prevention, Department of Health and Human Services, December 2002
[5] Jain, Tarun, M.D., Harlow, Bernard L., PhD and Hornstein, Mark D. M.D.; *Insurance Coverage and Outcomes of In Vitro Fertilization,* New England Journal of Medicine, Vol. 347, No. 9, August 29, 2002
[6] Pennsylvania Health Care Cost Containment Council, www.phc4.orf/reports/mandates/1183/Overview_of_Infertility.htm

total population and between 1.6% and 2.4% of the under-age sixty five population. In any given year, 3,500 to 4,000 Maine women can be expected to seek treatment.

In testimony given at the public hearing, an estimate of 12,000 Maine women who suffer from infertility was cited. However, there was no documentation supporting this estimate.

2. *The extent to which the service or treatment is available to the population.*

Infertile Maine couples currently rely on OB/GYN and family physicians for the first level of assistance. At the next level are OB/GYN or urologists who have a special interest in infertility and have established open lines of communication with specialists. Earlier this year, Maine's first gynecologic endocrinologist began practice at the Maine Medical Center in Portland. The majority of patients seeking care will be at these levels.

Currently there are no infertility clinics in Maine. However, all preparation for, and monitoring of treatment at clinics can be done in Maine. Massachusetts has seven infertility clinics that reported results for activities in 2000 and New Hampshire has one clinic that reported results.[7] These are the closest U.S. clinics. Of course, if this legislation is passed, it is possible that clinic(s) specializing in infertility treatments would locate in Maine.

3. *The extent to which insurance coverage for this treatment is already available.*

Most standard insurance policies do not provide for infertility benefits. However, infertility coverage is widely offered as an option to large employers.

Anthem Blue Cross Blue Shield's (Anthem) fully insured policies generally do not contain infertility benefits. Its HMO Choice product has an infertility optional rider that can be purchased by large employers. Coverage under the rider is at the plan level for diagnostic services, 50% coinsurance if treatment is referred from a participating provider, and 30% coinsurance if treatment is self-referred. It has a lifetime maximum of $20,000.
The state employee plan covers the treatment of infertility at a level of 80% to a lifetime limit of $20,000 when the treatment is referred by the primary care

[7] 2000 CDC Report

physician. There currently is no coverage for self-referred treatment.

Harvard Pilgrim's standard benefit plans in Maine limit coverage for infertility to consultations and evaluations only.

Most of Aetna's policies also limit infertility benefits to diagnosis and surgical treatment for the underlying medical cause. Very large groups can purchase a rider that will provide group members with enhanced infertility treatments. These treatments do not include the ART that are included in this proposed mandate. The rider also limits certain treatments, e.g., ovulation induction with menotropins, to a maximum of six cycles per lifetime. Large groups can purchase an additional rider for ART, which also limits the number of times certain ARTs will be covered.

CIGNA policies exclude infertility services unless an employer purchases optional coverage. The optional coverage typically sets a benefit limit, such as $20,000 per family per lifetime. This option is only available to large employers.

UHIC standard policies exclude infertility treatment. Groups with 50 or more employees may purchase a rider that limits benefits to $30,000 per year.

The 2002 National Survey of Employer-Sponsored Health Plans conducted by Mercer Human Resource Consulting shows the percentage of large employers in the northeast that cover various infertility services:

Service	**% of Employers that Cover[8]**
Evaluation by a Specialist	57%
Drug Therapy	39
Artificial Insemination	35
In Vitro Fertilization	29
ART other than In vitro	16
No fertility services	39

Only 29% of large groups, which presumably are self-funded and exempt from state mandates, choose to cover IVF. Only 16% of large groups cover ARTs other than IVF.

4. *If coverage is not generally available, the extent to which the lack of coverage*

results in a person being unable to obtain the necessary health care treatment.

Only 43% of infertile women raise the issue with their OB/GYN and only 21% of women are examined to determine the cause of their infertility.[9] Cost is a major barrier to women seeking infertility treatment. Some women seek treatment that is covered under standard insurance policies, such as treatment for the underlying cause. Procedures such as treatments for ovarian cysts, surgery of the fallopian tubes, pelvic laparoscopy are routinely covered under health insurance policies. Blackwell showed that the hidden cost of treating infertility ranged from $0.27 to $0.50 per member per month (PMPM) in 1996 dollars[10]. This equates to about $0.54 to $1.00 PMPM in 2003 dollars. These treatments are not necessarily the most cost efficient.

If families self-pay, they may rely more on drugs to stimulate egg production, (ovulation induction). According to testimony and subsequent submission by Dr. Peter M. Martin, ovulation induction is responsible for half the number of multiple pregnancies. The initial hospital costs of multiple deliveries from assisted reproductive cycles are estimated to have been $640 million during 2000 alone.[11]

Many couples will opt for services that are covered, even though they may be less appropriate. Tuboplasty which costs between $8,000 and $10,000 per surgery is covered under insurance plans even though most experts say that IVF, which is about the same cost, is more likely to result in a successful pregnancy.[12]

Dr. Tarun Jain, et.al., discovered that states that do not require insurance coverage for infertility procedures have the highest number of embryos transferred per cycle resulting in the highest rates of pregnancies and live births from IVF, but also the highest number of live births of multiple infants, especially three or more.[13]

Multiple births represent a short term and long term risk to the mother in the

[8] Mercer Human Resource Consulting, 2002 National Survey of Employer-Sponsored Health Plans
[9] William M. Mercer
[10] Blackwell, Richard E. and the William M. Mercer Actuarial Team, *Hidden Costs of Infertility Treatment in Employee Health Benefits Plans*, 2000
[11] Hogue, Carol J. Rowland, PhD, MPH, *Successful Assisted Reproductive Technology: The Beauty of One*. Obstetrics & Gynecology, November 2002, Volume 100, Number 5 Part 1
[12] RESOLVE of Washington, Applicant Report
[13] Jain, Tarun, M.D., Harlow , Bernard L., Ph. D., and Hornstein, Mark, M.D., *Insurance Coverage and Outcomes of In Vitro Fertilization*, New England Journal of Medicine, Vol. 347, No. 9, August, 2002

form of premature labor, premature delivery, pregnancy-induced hypertension, gestational diabetes and uterine hemorrhage. Children born premature are at higher risk for respiratory distress syndrome, intracranial hemorrhage, cerebral palsy, blindness, physical and mental developmental disabilities as well as death. Multiple births require a personal as well as financial cost for the parents.[14]

In 2000 the estimated costs per family of delivering multiple-gestation pregnancies resulting from ART procedures ranged from $58,865 for twins to $281,698 for quadruplets. The cost per delivery resulting from IVF pregnancies was about $39,000 for pregnancies with one or two fetuses and $340,000 per pregnancies with triplet and quadruplets.[15] Obstetrical and neonatal costs of quadruplets have exceeded $1,000,000.[16] It is in the best interest of everyone to minimize the number of multiple births.

5. *If coverage is not generally available, the extent to which the lack of coverage involves unreasonable financial hardship.*

Infertility treatments can be very costly. The simplest form of infertility treatment is the use of infertility drugs. These drugs can cost anywhere from $200 to $3,000 per month.[17] Without insurance coverage of those prescriptions, they are purchased without the benefit of a carrier's contracted price.

ART is part of infertility treatment. There are generally three types of ARTs; however, this is an evolving science:

- IVF involves combining a man's sperm and a woman's egg in a laboratory dish where fertilization occurs. The embryo is then transferred to the uterus to develop. The average cost is about $10,000 per cycle, not including blood testing or hormones, which can add $3,000 to $5,000 per cycle.[18] IVF was used in about 98% of ART cycles in 2000.[19]
- GIFT involves using a fiber-optic instrument to guide the transfer of the unfertilized eggs and sperm into the women's fallopian tubes

[14] Jain
[15] Wright, Victoria, C.M.P.H, Schieve, Laura A., Ph.D., Reynolds, Meredith A., PhD., Jeng, Gary, Ph.D., *Assisted Reproductive Technology Surveillance—United States, 2000*, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC
[16] Katz, Patricia, Nachtigali, Robert, Showstack, Jonathan, *The Economic Impact of the Assisted Reproductive Technologies.* Institute for Health Policy Studies, University of California, San Francisco, www.nature.com/fertility
[17] Pennsylvania Health Care Cost Containment Council
[18] Pascual, Psyche, *Financing Infertility Treatment*, A Healthy Me, www.ahealthyme.com
[19] 2000 CDC Report

through a small incision in her abdomen. The cost is $8,000 to $13,000 per cycle, not including blood testing or hormones.[20] In 2000 GIFT accounted for less than 1% of all ART cycles.[21]

- ZIFT involves fertilizing a woman's egg in the laboratory and then using a laparoscope to guide the transfer of the fertilized eggs (zygotes) into her fallopian tubes. In 2000 this represented about 1% of all ART cycles.[22] The cost, not including blood testing or hormones, is between $10,000 and $13,000 per cycle.[23]

The number of cycles required before a woman conceives varies by age. The following chart shows the percentage of cycles resulting in pregnancies by the age of the woman.

Age of Woman	% of Cycles Resulting in Pregnancies[24]
<35	37.6%
35-37	32.2
38-40	24.6
41-42	16.0
43	10.3
>43	6.1

In states that do not have any mandated infertility benefits, 25.7% of all cycles result in pregnancies.[25] If we assume the cost per cycle is about $13,000, then a family can expect to have four cycles before a pregnancy occurs. The cost would be about $52,000. Of course, this cost varies significantly by the age of the women. A woman under age 35 could expect a lower cost, while a woman age 44 could expect to pay four times as much.

The percentage of cycles resulting in pregnancies is higher in states without mandated infertility benefits. This is because the number of embryos transferred is greater than in states that have mandated infertility benefits. A higher number of embryos result in more multiple births. 11.2% of all pregnancies had three or more fetuses in states without mandated infertility.[26] Low weight babies and their accompanying complications are associated with multiple births. The cost of treating these babies is very high.

[20] Pennsylvania Health Care Cost Containment Council
[21] 2000 CDC Report
[22] 2000 CDC Report
[23] Pennsylvania Health Care Cost Containment Council
[24] 2000 CDC Report
[25] Jain
[26] Jain

In lieu of ART treatments, women may opt for drug therapy, which can cost $3,000 per cycle and results in the greatest number of multiple births.

6. *The level of public demand and the level of demand from providers for this treatment or service.*

There are currently no infertility clinics in Maine, which implies that there is not a huge demand from providers for treatment of infertility services. The number of Maine citizens impacted by this bill is small, so the public demand is limited.

7. *The level of public demand and the level of demand from the providers for individual or group coverage of this treatment.*

Several members of the public testified in support of LD 213. One woman told of losing coverage for infertility prescriptions when her insurance changed pharmacy benefit managers (PBM). Her out of pocket costs were $1,500 for the injectable drug which required two inseminations 24 hours apart each cycle. After complaining, she had the coverage reinstated. After nine inseminations, she moved to IVF, which was successful.

In another case, the woman had a condition that impairs proper ovarian function. She underwent surgery, which was paid by insurance. When that did not work, she had a choice of injection at $3,500 per cycle, which were not covered by insurance, or IVF, which is also not covered.

One lady testified that they would not have been able to fund three IVF attempts unless her husband's insurance included infertility benefits.

Another testified that she became sterile after radiation treatment for cancer in her early twenties. Her only hope of becoming a mother is to have IVF with her sister's egg and her husband's sperm. They need benefits to be able to accomplish this.

Some testified to the psychological impact infertility has on a couple.

Anthem testified regarding the cost of such a mandate. They also referred to research that shows the incidence of birth defects is significantly higher for

babies born using ART.

8. *The level of interest in and the extent to which collective bargaining organizations are negotiating privately for the inclusion of this coverage by group plans.*

No information is available.

9. *The likelihood of meeting a consumer need as evidenced by the experience in other states.*

There is a wide range of costs from states that have full or partial infertility mandates. In its analysis of a proposed infertility mandate, the Washington State Department of Health shows the following costs of infertility benefits:

Cost of Infertility Benefits in Other States

State	**$ Per Member Per Year**[27]
Iowa	$8.40
Massachusetts	27.00
Delaware	7.20
Minnesota	13.80
Illinois	21.50

Harvard Pilgrim indicated its cost for ART only (does not include other infertility treatment) in Massachusetts for 2002 was $10.68 per member per year. Blue Cross Blue Shield of Massachusetts' cost for 2002 for infertility treatment was $21.60. CIGNA indicated their 2002 cost was 5% of premium. It is unclear if any of the costs included an estimate for increased higher risk pregnancies and increased multiple births.

[27] Washington State Department of Health, *Infertility Mandated Benefits Sunrise Review*, January 2001

Aetna has recently completed an actuarial study of the impact of the infertility law passed in New Jersey effective in January 2002. Their experience shows that the frequency of multiple births more than doubled, increasing by 124%. The cost of neonatal unit care increased by 72%. Both increases are assumed to be attributable to the increased use and payment thereof of mandated infertility services.

10. The relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.

No information is available.

11. Alternatives to meeting the identified need.

The lack of insurance has forced many infertility clinics to provide financial planning assistance when patients first come. Some clinics will offer an extended payment plan. Most accept credit cards and some help arrange funding from third parties. Some clinics are providing flexible payment programs for patients without insurance. One program, developed by Advanced Reproductive Care, Inc., based in San Francisco has spread to 90 clinics nationwide.

A new program at some clinics is called the refund guarantee, or shared-risk program. A woman pays for a specific number of cycles, say three. If she gets pregnant on the first, she still pays for three. But if at the end of three cycles she is not pregnant, she receives a refund of the majority of the cost.[28]

Women who are older than 45 will not receive benefits under this proposed mandate. They will have to continue to self-fund. Women who have one living child will be limited to two cycles for ART. If these are not successful, or if the woman wants a third child, they will have to continue to self-fund.

12. Whether the benefit is a medical or a broader social need and whether it is inconsistent with the role of insurance and the concept of managed care.

The treatment of infertility is an emotional issue. In its report, Pennsylvania included the following regarding medical necessity:[29]

[28] Pascual
[29] Pennsylvania Health Care Cost Containment Council

> "The sense of loss at not being able to enter in on the joys of parenthood is profound and one cannot underestimate the concern and grief that it may engender. On the other had, from a medical necessity standpoint, the medical immediacy of curing the inability to get pregnant is probably rather low in most cases; and
>
> While infertility benefits may enhance quality of life, infertility is not a life-threatening medical condition; and
>
> While arguments and analyses in support of health insurance for IVF are in some ways compelling, they are unlikely to persuade many private health insurers who view the procedure as both costly and discretionary."

Washington State concluded that scientific evidence implies that infertility is not a disease, but a symptom of another medical problem. This was one of the reasons it recommended not passing a mandate.[30]

The State of New York also reviewed mandated infertility benefits. While the (New York) task force recognized that without insurance coverage for ARTs, some individuals will resort to riskier and possibly less effective medical interventions that could increase the possibility of multiple births, they could not justify legislation that gives priority to ART when so many other basic health care needs remain unmet.[31]

Proponents refer to Mayo Clinic's definition of infertility as a bona fide disease. Mayo Clinic defines infertility as the "inability to conceive a child within one year of trying. Infertility is a complex disease and is often due to numerous factors."[32]

Forty percent of infertility cases are related to male factors, 50% to female factors and 10% are unknown.[33] The most common cause of male infertility is varicose veins in the scrotal sac, which accounts for 30% to 50% of cases. The most common causes of female infertility are ovulatory problems (39%), tubal damage (30%), coital/cervical problems (18%) and endometriosis (13%).[34] Some proponents assert that if the underlying cause is medical, then the "cure" should be covered.

Others may perceive the age limit and cycle limits as arbitrary.

13. The impact of any social stigma attached to the benefit upon the market.

[30] Washington State Department of Health, *Infertility Mandated Benefits Sunrise Review*
[31] Washington State Department of Health
[32] Mayo Clinic website, www.mayoclinic.org/infertility-sct/
[33] Mercer

The testimony given showed the psychological impact of being childless in a society that values family. However, the acceptance of multiple births associated with ART is waning as health care cost increases are forcing employers to increase cost sharing to employees and dependents.

14. *The impact of this benefit upon the other benefits currently offered.*

There will be more higher risk pregnancies, more multiple births and more low birth weight babies that require extraordinary resources initially than there would be without any mandate. The very high initial costs of care for these babies could result in some exceeding the lifetime maximum and being without coverage.

Some of the cost of ART could be offset due to the very high incidence of high-order multiple births when using ovulation induction only which is responsible for many multiple births. Ovulation induction is the first method of choice in absence of infertility benefits.

Evidence shows that the risk of birth defects increase with ART. This could result in additional long term medical benefits.

There is some indication that ART procedures may replace some tubal surgery. Some cost savings may be realized especially if the tubal surgery is extensive or done more than once. Currently tubal surgery is more often covered by insurance and therefore sometimes used even though IVF may be more effective.

15. *The impact of the benefit as it relates to employers shifting to self-insurance and the extent to which the benefit is currently being offered by employers with self-insured plans.*

The 2002 Mercer/Foster Higgins National Survey of Employer-sponsored Health Plans indicates that over 50% percent of the large employers (500 or more employees) in the Northeast self-insure health plans. 39% of large employers in the northeast do not offer any type of infertility benefits. This mandate could be an incentive for some employers that are currently insured to become self-funded to avoid the direct and indirect costs (greater frequency of multiple births and low weight newborns).

16. *The impact of making the benefit applicable to the state employee health insurance*

[34] Mercer

program.

The State Employee Health Insurance Plan currently covers the treatment of infertility at a level of 80% to a lifetime limit of $20,000 when the treatment is a primary care physician referred benefit. There currently is no coverage for self-referred treatment. Additionally, the benefit is limited to in IVF, artificial insemination or GIFT treatment for one of the following reasons:

1. absent or irreparably damaged fallopian tubes or severe tubal disease
2. low male sperm count
3. idiopathic infertility.

Anthem estimated that LD 213 would increase the cost of the State Employee Health Insurance Plan by about $1.00 PMPM, or 0.33%.[35] This estimate assumed that 350 members per year would seek infertility treatments and that 35 would use ART, based on national data. However, this data does not reflect the demographics of the state employee plan, which includes a large proportion of retirees. Data from the Maine Health Information Center shows that the actual number of members of the state employee plan that used the existing infertility benefit was 114 in 2001 and 128 in 2002. If utilization under LD 213 is similar, it would reduce the estimated impact on the state employee plan to 0.12%.

[35] Whitmore, William of Anthem; Fiscal Note L D 213

IV. Financial Impact

B. Financial Impact of Mandating Benefits.

1. The extent to which the proposed insurance coverage would increase or decrease the cost of the service or treatment over the next five years.

There is evidence that the cost per cycle does not vary significantly from states that have mandated infertility benefits and states that have no such mandate.[36] Therefore, the presence of insurance does not appear to significantly impact the cost per cycle. However, the number of cycles per course of treatment may increase as a result of the mandate, thereby increasing the total cost.

2. The extent to which the proposed coverage might increase the appropriate or inappropriate use of the treatment or service over the next five years.

There are almost three times as many ART cycles completed per 1,000 women of childbearing ages in states that have unlimited infertility benefits mandated compared to the frequency in states with no mandate. The cost per cycle is about the same. The total cost of treatment is higher, because of the greater number of cycles. However, there are also fewer multiple births, which help to offset the higher number of cycles.

In states that have some infertility benefits, similar to the proposed legislation in Maine, the number of ART cycles per 1,000 women of childbearing age is about 20% higher.[37]

Providing infertility benefits can reduce the incidence of multiple births associated with ART. However, ART does result in a significantly higher frequency of multiple births. Access to infertility treatment will increase the number of multiple births in aggregate, but should result in a lower frequency for women who would have sought infertility treatment via self pay.

Multiple births are coupled with low birth weight. The cost for caring for low birth weight babies is very high, not to mention the accompanying disabilities.

[36] Jain
[37] Jain

The language in the proposed bill limits the number of cycles for ART. This can be self-defeating. If women know they only have a limited number of cycles, they are more willing to transfer a higher number of embryos. One study showed that the number of embryos transferred per cycle was higher and the percentage of pregnancies with three or more fetuses was higher when women had to self-fund the treatment.[38] This supports the hypothesis that limitations can result in greater overall costs associated with multiple births.

3. *The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.*

The treatment may substitute for tubal surgeries, which are often as expensive as the first ART cycle and have slightly less success in achieving pregnancies.[39] In the testimony given at the hearing, some women indicated that they used infertility drugs, because that is what their insurance covered. Infertility drugs may not be the best treatment for some types of infertility. Less than 50% of infertile couples are successful in achieving a live birth with methods of treatment such as ovulation induction (drugs), donor insemination and surgery.[40]

Mandating coverage of ART procedures would reduce the reliance on ovulation induction and allow patients to use to IVF. Multiple births using IVF can be reduced by limiting the number of embryos that are transferred in each cycle. However, the success rate for pregnancy is also reduced, requiring more cycles. The incidence of septuplets and octuplets are associated almost exclusively to ovulation induction via drugs.

4. *The methods which will be instituted to manage the utilization and costs of the proposed mandate.*

LD 213, section 3.B.5 requires ART treatment to be "performed at medical facilities that conform to the American Society for Reproductive Medicine (ASRM) guidelines…" These guidelines, in addition to staffing requirements/credentialing, laboratory standards and practices, include a recommendation for limitations on embryo transfer number based on the prognosis for success:

[38] Jain
[39] Applicant Report submitted by RESOLVE of the State of Washington
[40] Collina, John. M.D., *Cost-effectiveness of In Vitro Fertilization*, Seminars in Reproductive Medicine, Volume 19,

Prognosis	Maximum Number of Embryos
Most Favorable	2
Above average	3
Average	4
Below Average	5

While these guidelines would reduce the number of embryos transferred (and thereby the multiple pregnancy rate), they are difficult to interpret, must rely on clinic-specific results, and are more lenient than most leaders in the field currently recommend. Also, the guidelines are voluntary, with many clinics *averaging* embryo transfer numbers in excess of the recommendations.[41]

The bill also limits benefits for women under age 45. Costs for successfully treating older women for infertility are significantly higher than the costs for treating younger women. There are lifetime maximums on the number of cycles and these vary by whether or not the woman has a living child. It is unclear whether this last limitation will survive a court challenge as being discriminatory.

CIGNA, which does not support the mandate, recommended limiting the coverage to $20,000 per family per lifetime.

Harvard Pilgrim, which did not support the legislation, suggested removing references to gestational carriers and to include verbiage explicitly stating that coverage is not required for the reversal of voluntary sterilization or any form of surrogacy.

Anthem does not support the legislation or any alternative mandate because of the potential for significant increases in claim costs. Their main concern is the indirect costs associated with multiple births.

UHIC recommended that the proposed mandate not be approved. However, if it is, they recommend the limit on the number of procedures be reduced by ½ and the lifetime maximum benefit for all procedures, including drugs, be $15,000.

5. *The extent to which insurance coverage may affect the number and types of*

Number 3, 2001
[41] Dr. Peter F. Martin

providers over the next five years.

Currently there are no infertility clinics located in Maine. There are clinics in New Hampshire and Massachusetts. Passage of this mandate could encourage infertility clinics to open.

6. *The extent to which the insurance coverage of the health care service or provider may be reasonably expected to increase or decrease the insurance premium or administrative expenses of policyholders.*

We have estimated that the direct costs, prior to any consideration of credit for services that may already be provided under different diagnosis, will range from $1.82 PMPM to $2.36 PMPM. This includes an estimate of 12% for administrative costs. If we assume that there is already about $1.14 PMPM ($1.00 ÷.88) in the claims for infertility type procedures, the net direct costs will be between $0.69 PMPM to $1.22 PMPM, or 0.3% to 0.5% of premium.[42] The range in premium is directly related to the range in utilization of services.

The indirect costs for this benefit are significant. Maternity costs for women who become pregnant using ART are significantly higher than normal. Although births from ART account for less than 1% of all live births, they now account for about a third of all twin births and more than 40% of triplets and higher[43] In developing our estimate of indirect costs, we assumed that 55.9% of all live births will be a single child, 38% would be twins and 6.1% would be births of three or more.[44] We used the same range of cycles as we assumed for the direct costs.

These indirect costs range from $1.55 PMPM to $2.30 PMPM or 0.6% to 0.9% of premium. These estimates include a 12% allowance for administrative costs.

Two adjustments to this estimate, one increase and one decrease, were not made and are assumed to offset each other. We have not included an estimate for the additional pregnancies resulting from treatments other than ART. Statistics for this incidence are very difficult to obtain because, unlike fertility clinics, which

[42] Numbers may not add due to rounding.
[43] Hogue
[44] Wright, Victoria, C.M.P.H., Schieve, Laura A, Ph.D., Reynolds, Meredith A., Ph.D., Jeng, Gary, Ph.D., *Assisted Reproductive Technology Surveillance—United States, 2000*, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC

are required to report statistics to the Centers for Disease Control (CDC), there are no reporting requirements for less intensive treatments. On the other hand, we have not incorporated an offset for the pregnancies already covered by women who have elected to self-fund treatment.

There is evidence that the frequency of birth defects is significantly higher for babies conceived using ART than babies conceived naturally. In a national registry of patients with Beckwith-Wiedemann Syndrome, conception with IVF was six times more likely. A large study published in the New England Journal of Medicine found that infants conceived through IVF have twice as high a risk of having a major birth defect -- such as a heart condition, or central nervous system abnormality -- as naturally conceived infants. A study by the federal Centers for Disease Control and Prevention discovered that, contrary to what many doctors had assumed, even singleton IVF babies, rather than only twins and other multiples, are twice as likely to be born at very low birth weights than other children.[45] Because of the difficulties in estimating the increased lifetime costs associated with birth defects, we have not explicitly included this in our estimate of indirect costs. Instead, we have reflected this additional cost by using the high end of the range determined for other direct and indirect costs.

There is a significant amount of variance for all of these estimates. For example, about 25% of all ART cycles result in pregnancy. Yet for older women, this number is much smaller, as low as 6%. Therefore the costs for infertility benefits for any one group could be four times the estimate provided here. Also, the variance in costs to treat multiple births is large. Neonatal care for births with greater than three babies can easily cost $1 million. The cost estimate used in this estimation was about $500,000.

Our estimate for the total, direct and indirect, cost for this proposed mandate is $3.53 PMPM, or 1.4% of premium.

The demand for infertility treatment is increasing. Success of infertility treatment is directly related to the age of the mother. Success drops significantly as the women ages. As more and more women delay having children, the demand will increase.

The estimated costs provided by the insurance carriers vary significantly.

[45] Marcus, Amy Dockser, "Does IVF Cause Birth Defects?", Wall Street Journal, September 16, 2003

Anthem does not provide for infertility benefits as described in the proposed mandate to fully insured groups. Some large experience rated groups have chosen to cover infertility benefits. Generally the benefits included services for diagnosis and treatment with lifetime maximum of $20,000. The experience for this benefit is $0.60 per member per month. This does not include any estimate for indirect costs.

Anthem estimated the total impact on premium would vary between $1.30 and $2.70 PMPM. This represents 0.8% to 1.71% of premium, depending upon the underlying health plan benefit.

UHIC provided the following cost estimates:

Plan Description	$PMPM	% of Net Total Claims
$250 Ded, 10% coinsurance $2,000 out-of-pocket	$4.28	2.23%
$500 Ded., 20% coinsurance, $2,500 out-of-pocket	$3.75	2.17%

UHIC's estimate includes indirect costs. The direct costs would be about 55% of total costs.

CIGNA's estimates are:

PMPM Impact	Large Group	Flex/Network	Small Group	Direct
Premium	$12.54	$10.45	$16.66	$28.77
Admin	1.00	0.52	2.58	4.46
Impact as % of Revenue				
Premium	3.87%	3.26%	4.60%	3.87%
Admin	0.31	0.17	0.71	0.60

CIGNA provided an estimate for direct pay, but the scope of the mandate is limited to group insurance. It also did not indicate whether the estimates included indirect costs. From their magnitude, we are assuming they do.

Aetna estimated the impact of the law to be a total of $8.79 PMPM. This is comprised of $7.16 for claims and $1.63 for administrative costs. They indicate this estimate may be low because it is based upon Aetna's utilization and cost is based upon infertility services provided only to women over age 35. This estimate does not reflect the cost of increased

maternity care or multiple births.

7. *The impact of indirect costs, which are costs other than premiums and administrative costs, on the question of the cost and benefits of coverage.*

There are significant indirect costs associated with this proposed legislation. Multiple births represent a short term and long term risk to the mother in the form of premature labor, premature delivery, pregnancy-induced hypertension, gestational diabetes and uterine hemorrhage. Children born premature are at higher risk for respiratory distress syndrome, intracranial hemorrhage, cerebral palsy, blindness, physical and mental developmental disabilities as well as death. Multiple births require a personal as well as financial cost for the parents.[46]

In 2000 the estimated costs per family of delivering multiple-gestation pregnancies resulting from ART procedures range from $58,865 for twins to $281,698 for quadruplets. The cost per delivery resulting from IVF pregnancies was about $39,000 for pregnancies with one or two fetuses and $340,000 per pregnancies with triplet and quadruplets.[47] Obstetrical and neonatal costs of quadruplets have exceeded $1,000,000.[48]

As stated in the answer to the previous question, there is evidence that the frequency of birth defects is significantly higher for babies conceived using ART than babies conceived naturally.

In our analysis, we incorporated the higher costs associated with prenatal and delivery of ART pregnancies. Due to a lack of reliable data, we neither reduced our estimate to reflect ART pregnancies already occurring without a mandate nor did we increase our estimate to incorporate pregnancies from other types of infertility treatment or the higher costs associated with birth defects. As discussed above, the first two omissions are assumed to offset each other and the costs from birth defects is reflected by using the high end of the range to estimate the other costs associated with the mandate. Therefore,

[46] Jain
[47] Wright
[48] Katz, Patricia, Robert Nachtigali, Jonathan Showstack, *The Economic Impact of the Assisted Reproductive Technologies,* Institute for Health Policy Studies, University of California, San Francisco, www.nature.com/fertility

our estimate for indirect costs is $2.30 PMPM or 0.9% of premium, including a 12% allowance for administrative costs.

8. *The impact on the total cost of health care, including potential benefits and savings to insurers and employers because the proposed mandated treatment or service prevents disease or illness or leads to the early detection and treatment of disease or illness that is less costly than treatment or service for later stages of a disease or illness.*

Our estimate of the total direct and indirect costs, prior to consideration of any savings, is $55.92 per member per year, or $4.66 PMPM. As stated previously, there could be about $1.00 PMPM already hidden in claim costs for infertility. The total cost, after this consideration, is $3.53 PMPM, or $42.32 per year.

Company	Estimate ($PMPM)
Mercer	$3.53
Aetna	$8.79
CIGNA	$10.97 - $19.24
Anthem	$1.30 – $2.70[1]
Harvard Pilgrim	$0.89[2]
UHIC	$3.73 – $4.28[3]

[1]Does not include administration
[2]Reflects ART only
[3]Does not include administration

Only UHIC indicated they had included an estimate for the indirect costs.

9. *The effects of mandating the benefit on the cost of health care, particularly the premium and administrative expenses and indirect costs, to employers and employees, including the financial impact on small employers, medium-sized employers and large employers.*

The cost to employers would vary by size. CIGNA estimates that the cost for large group HMO will be 4.18%, small group 5.31% and its network will be 3.43%. They indicated their cost for infertility treatment in Massachusetts is 5% of premium. UHIC did not vary their cost by group size, but by benefit. The average increase was 2.2%. Aetna and Harvard only provided a cost PMPM. Anthem estimated the mandate would be about 0.9% for small group and slightly less for large group.

We estimate the cost to be about 1.4% for small groups. The aggregate impact on large groups will be less because some large groups currently provide infertility benefits. In the northeast region, 29% of large employers currently provide in IVF, although only

16% provide for other ARTs other than IVF.

10. *The effect of the proposed mandate on cost-shifting between private and public payors of health care coverage and on the overall cost of the health care delivery system in this State.*

To our knowledge, there currently are not any public payors, other than the State Employee Health Insurance Plan, that fund infertility benefits. Medicare and Medicaid (MaineCare) do not provide coverage for infertility benefits. Therefore, the legislation is expected to have no impact on cost-shifting between the private and public payors.

V. Medical Efficacy

C. The Medical Efficacy of Mandating the Benefit.

1. The contribution of the benefit to the quality of patient care and the health status of the population, including any research demonstrating the medical efficacy of the treatment or service compared to the alternative of not providing the treatment or service.

In its Applicant Report to the State of Washington when it was considering an infertility mandate, RESOLVE of Washington referenced a Harvard University study that showed infertile women have global symptom scores equivalent to cancer, cardiac rehabilitation and hypertension patients.[49] The study concluded that infertile couples have similar psychological symptoms as other medical conditions and therefore psychological interventions for serious medical illness should be applied in infertility treatment.[50]

The Pennsylvania Health Care Cost Containment Council concluded that "though infertility frustrates a basic human desire, it is not generally a threat to a person's physical well being. While infertility has a significant emotional impact upon patients and is a medical condition for which treatments are available, infertility is not a life-threatening medical condition." The Council recommended not incorporating infertility coverage into their mandated benefits.

There are two potential results of not providing infertility benefits. One, infertile couples will not have children. Quantifying the psychological and medical costs associated with this is extremely difficult. Two, some couples will self-fund infertility treatment. The most economical approach is to use fertility drugs and/or transfer a significant number of embryos to increase the chance of pregnancy. This can result in multiple births, whose costs will be covered under the medical plan. The incidence of multiple births is low, even with infertility treatments. Once a multiple birth occurs, however, the costs are usually very high.

[49] Global symptom scores reflect the number of physical and mental conditions, such as energy level, bruising, mood, that impacts the quality of life. A high score means there are many symptoms.
[50] RESOLVE

2. *If the legislation seeks to mandate coverage of an additional class of practitioners relative to those already covered.*

   a. *The results of any professionally acceptable research demonstrating medical results achieved by the additional practitioners relative to those already covered.*

      This is not applicable since the legislation does not mandate coverage of an additional class of practitioners.

   b. *The methods of the appropriate professional organization that assure clinical proficiency.*

      This is not applicable since the legislation does not mandate coverage of an additional class of practitioners.

VI. Balancing the Effects

D. The Effects of Balancing the Social, Economic, and Medical Efficacy Considerations.

1. The extent to which the need for coverage outweighs the cost of mandating the benefit for all policyholders.

Mandating infertility benefits is an emotional issue. The joys of parenthood are unquantifiable. A couple can live without children, although for those who desire them, infertility is a difficult reality. Some religions, such as Catholicism, are opposed to ART treatments.

Costs are often cited as a reason not to cover infertility treatments. According to the 1997 William M. Mercer report, Infertility as a Covered Benefit, infertility treatment can be delivered cost effectively by establishing treatment guidelines, limiting the number of embryos transferred and thereby lowering the chance of multiple births and associated high cost. This paper also recommends controlling costs by limiting the number of cycles, number of procedures, the number of months of therapy and limit the overall costs.

Limiting the number of lifetime cycles encourages the transference of too many embryos, especially if a woman is facing the limit. This, in turn, can increase the incidence of multiple births. Not including infertility treatments causes infertile couples to rely heavily on infertility drugs, which do result in multiple births.

There is evidence that the incidence of birth defects increases with the use of ART. This may be a reason not to encourage its usage via coverage.

2. The extent to which the problem of coverage can be resolved by mandating the availability of coverage as an option for policyholders.

If this benefit is to be provided as a mandatory offer as opposed to a mandatory benefit, then the costs could be higher because only those who perceive a need will purchase the coverage. This will be particularly true for small groups where the risks cannot be spread across the entire pool.

3. *The cumulative impact of mandating this benefit in combination with existing mandates on costs and availability of coverage.*

It is not possible to precisely measure the impact of mandated benefits. However, it is possible to estimate an outside limit, the maximum possible increase in health insurance premiums resulting from mandates. Because various mandates apply to different categories of coverage, this maximum likewise varies. The Bureau's estimates of the maximum premium increases due to existing mandates and the proposed mandate are displayed in Table A.

TABLE A – MAXIMUM PREMIUM INCREASES

	Group (more than 20 employees)	Group (20 or fewer employees)	Individuals
Current Mandates			
Fee-for-Service Plans	10.29%	4.55%	3.32%
Managed Care Plans	9.09%	4.18%	3.24%
LD 213			
Fee-for-Service Plans	1.08%	1.40%	n/a
Managed Care Plans	1.08%	1.40%	n/a
Cumulative Impact			
Fee-for-Service Plans	11.48%	6.01%	3.32%
Managed Care Plans	10.27%	5.64%	3.24%

Due to a lack of reliable data, our estimates for LD 213 did not incorporate the higher costs associated with other types of infertility treatment or with birth defects. To offset these omissions, we have used the high end of the range to estimate the other costs associated with the mandate in Table A.

The estimated cost of current mandates is detailed in Appendix B. For most of these mandates, our estimate is based on the net impact on premiums as estimated at the time the mandate was enacted. However, four of the most costly mandates – mental health, substance abuse, chiropractic, and screening mammograms – were enacted before cost estimates were required. These four statutes require carriers to report annually the amount of claims paid for these benefits. Our estimates are based on these reports. However, the true cost of these four mandates impact is less than this for two reasons:

1. Some of these services would likely be provided and reimbursed even in the absence of a mandate, although we have tried to reflect some of this in the cost; and

2. It has been asserted (and some studies confirm) that covering certain services or providers will reduce claims in other areas. For instance, covering mental health and substance abuse may reduce claims for physical conditions. Covering social workers may reduce claims for more expensive providers such as psychiatrists and psychologists. Covering chiropractic services may reduce claims for back surgery. Covering screening mammograms may reduce claims for breast cancer treatment.

While both of these factors reduce the cost impact of the mandates, we are not able to estimate the extent of the reduction at this time. However, a recent General Accounting Office (GAO) report[51] gives some indication of the magnitude of the reduction. The GAO report used the terms "total cost" and "marginal cost" in discussing item (1) above. The total cost is the cost of the benefits that are mandated. The marginal cost is the difference between this cost and that portion that would have been covered even without the mandate. The GAO report cited two studies that estimated the marginal cost:

- Maryland, which has more mandated benefits than any other state, found that the total costs of its mandates were about 15% of premiums, while the marginal costs were about 4.2%.[52]

- In a 2000 report, the Congressional Budget Office (CBO) concluded that the total cost of state mandates ranged from 5.4% to 22.0% of total claim costs while the marginal cost ranged from 0.28% to 1.15%.[53]

[51] General Accounting Office, *Private Health Insurance: Federal and State Requirements Affecting Coverage Offered by Small Businesses*, 2003
[52] Mercer Human Resource Consulting, *Mandated Health Insurance Services Evaluation*, prepared at the request of the Maryland Health Care Commission, 2002
[53] Congressional Budget Office, *Increasing Small-Firm Health Insurance Coverage Through Association Health Plans and HealthMarts*, 2000

VII. Appendices

Appendix A: Letter Requesting Study with Proposed Legislation

Appendix B: Cumulative Impact of Mandates

Following are the estimated costs for the existing mandates. The estimates for mental health, substance abuse, chiropractic, and screening mammography reflect the total cost of the benefits mandated. Estimates for other mandates reflect the impact of the mandate net of benefits that would have been covered even without the mandate.

- ***Mental Health*** (Enacted 1983) – The mandate applies only to groups of more than 20. Mental health parity for listed conditions was effective 7/1/96. The list of conditions for which parity is required was expanded effective 10/1/03. The amount of claims paid has been tracked since 1984 and has historically been in the range of 3% to 4% of total group health claims. The percentage had been decreasing in recent years from a high of 4.16% in 1997 to 3.27% in 2000, but held steady at 3.33% in 2001 and 2002. For 2001, this broke down as 3.22% for HMOs and 3.67% for indemnity plans. For 2002, this disparity increased to 2.72% for HMOs and 5.11% for indemnity plans. We assume an average of the 2001 and 2002 levels going forward, but add ¾ of a percentage point to reflect the expansion of the list of conditions for which parity is required. Although it is likely that some of these costs would be covered even in the absence of a mandate, we have no basis for estimating how much. We have included the entire amount, thereby overstating the impact of the mandate to some extent.

- ***Substance Abuse*** (Enacted 1983) – The mandate applies only to groups of more than 20 and originally did not apply to HMOs. Effective 10/1/03, substance abuse was added to the list of mental health conditions for which parity is required. This applies to HMOs as well as indemnity carriers. The amount of claims paid has been tracked since 1984. Until 1991, it was in the range of 1% to 2% of total group health claims. This percentage showed a downward trend from 1989 to 2000 when it reached 0.31% and increased to 0.37% in 2001 and to 0.66% in 2002. The long-term decrease was probably due to utilization review, which has sharply reduced the incidence of inpatient care. Inpatient claims decreased from about 93% of the total in 1985 to about 55% in 2001 but increased to 62% in 2002. The 0.66% for 2002 broke down as 0.62% for HMOs and 0.77% for indemnity plans. We estimate substance abuse benefits to remain at the current level, but add ¼ of a percentage point to reflect the expansion of the list of conditions for which parity is required. Although it is likely that some of these costs would be covered even in the absence of a mandate, we have no basis for estimating how much. We have included the entire amount, thereby overstating the impact of the mandate to some extent.

- ***Chiropractic*** (Enacted 1986) – The amount of claims paid has been tracked since 1986 and

has been approximately 1% of total health claims each year. However, the percentage increased from 0.84% in 1994 to 1.51% in 2000. Since then, it decreased to 1.32% in 2001 and then increased to 1.45% in 2002. The level varies significantly between group and individual and between HMOs and indemnity plans. We estimate that going forward. The level will be continue at the 2002 level of 1.56% for group HMO plans, 1.31% for group indemnity plans, 0.35% for individual HMO plans, and 0.46% for individual indemnity plans. Although it is likely that some of these costs would be covered even in the absence of a mandate, we have no basis for estimating how much. We have included the entire amount, thereby overstating the impact of the mandate to some extent.

- ***Screening Mammography*** (Enacted 1990) – The amount of claims paid has been tracked since 1992. It increased from 0.11% of total claims in 1992 to 0.59% in 2001, which may reflect increasing utilization of this service. 2002 figures are not comparable to earlier years because one major company erroneously included Medicare supplement business in previous reports. The 2002 figure of 0.7% is therefore more accurate. This figure broke down as 0.72% for group HMO plans, 0.65% for group indemnity plans, .43% for individual HMO plans, and 0.73% for individual indemnity plans. The individual HMO data is not credible and the other variations are insignificant. We estimate the 0.70% in all categories going forward. Although it is likely that some of these costs would be covered even in the absence of a mandate, we have no basis for estimating how much. We have included the entire amount, thereby overstating the impact of the mandate to some extent.

- ***Dentists*** (Enacted 1975) – This mandate requires coverage to the extent that the same services would be covered if performed by a physician. It does not apply to HMOs. A 1992 study done by Milliman and Robertson for the Mandated Benefits Advisory Commission estimated that these claims represent 0.5% of total health claims and that the actual impact on premiums is "slight." It is unlikely that this coverage would be excluded in the absence of a mandate. We include 0.1% as an estimate.

- ***Breast Reconstruction*** (Enacted 1998) – At the time this mandate was being considered in 1995, Blue Cross and Blue Shield of Maine estimated the cost at $0.20 per month per individual. We have no more recent estimate. We include 0.02% in our estimate of the maximum cumulative impact of mandates.

- ***Errors of Metabolism*** (Enacted 1995) – At the time this mandate was being considered in 1995, Blue Cross estimated the cost at $0.10 per month per individual. We have no more recent estimate. We include 0.01% in our estimate.

- ***Diabetic Supplies*** (Enacted 1996) – Our report on this mandate indicated that most of the 15

carriers surveyed in 1996 said there would be no cost or an insignificant cost because they already provide coverage. One carrier said it would cost $.08 per month for an individual. Another said .5% of premium ($.50 per member per month) and a third said 2%. We include 0.2% in our estimate.

- ***Minimum Maternity Stay*** (Enacted 1996) – Our report stated that Blue Cross did not believe there would be any cost for them. No other carriers stated that they required shorter stays than required by the bill. We therefore estimate no impact.

- ***Pap Smear Tests*** (Enacted 1996) – No cost estimate is available. HMOs would typically cover these anyway. For indemnity plans, the relatively small cost of this test would not in itself satisfy the deductible, so there would be no cost unless other services were also received. We estimate a negligible impact of 0.01%.

- ***Annual GYN Exam Without Referral*** (managed care plans) (Enacted 1996) – This only affects HMO plans and similar plans. No cost estimate is available. To the extent the PCP would, in absence of this law, have performed the exam personally rather than referring to an OB/GYN, the cost may be somewhat higher. We include 0.1%.

- ***Breast Cancer Length of Stay*** (Enacted 1997) – Our report estimated a cost of 0.07% of premium.

- ***Off-label Use Prescription Drugs*** (Enacted 1998) – The HMOs claimed to already cover off-label drugs, in which case there would be no additional cost. However, providers testified that claims have been denied on this basis. Our 1998 report did not resolve this conflict but stated a "high-end cost estimate" of about $1 per member per month (0.6% of premium) if it is assumed there is currently no coverage for off-label drugs. We include half this amount, or 0.3%.

- ***Prostate Cancer*** (Enacted 1998) – No increase in premiums should be expected for the HMOs that provide the screening benefits currently as part of their routine physical exam benefits. Our report estimated additional claims cost for indemnity plans would approximate $0.10 per member per month. With the inclusion of administrative expenses, we would expect a total cost of approximately $0.11 per member per month, or about 0.07% of total premiums.

- ***Nurse Practitioners and Certified Nurse Midwives*** (Enacted 1999) – This law mandates coverage for nurse practitioners and certified nurse midwives and allows nurse practitioners to serve as primary care providers. This mandate is estimated to increase premium by 0.16%.

- ***Coverage of Contraceptives*** (Enacted 1999) – Health plans that cover prescription drugs are required to cover contraceptives. This mandate is estimated to increase premium by 0.8%.

- ***Registered Nurse First Assistants*** (Enacted 1999) – Health plans that cover surgical first assisting are mandated to cover registered nurse first assistants if an assisting physician would be covered. No material increase in premium is expected.

- ***Access to Clinical Trials*** (Enacted 2000) – Our report estimated a cost of 0.46% of premium.

- ***Access to Prescription Drugs*** (Enacted 2000) – This mandate only affects plans with closed formularies. Our report concluded that enrollment in such plans is minimal in Maine and therefore the mandate will have no material impact on premiums.

- ***Hospice Care*** (Enacted 2001) – No cost estimate was made for this mandate because the Legislature waived the requirement for a study. Since carriers generally cover hospice care already, we assume no additional cost.

- ***Access to Eye Care*** (Enacted 2001) – This mandate affects plans that use participating eye care professionals. Our report estimated a cost of 0.04% of premium.

- ***Dental Anesthesia*** (Enacted 2001) – This mandate requires coverage for general anesthesia and associated facility charges for dental procedures in a hospital for certain enrollees for whom general anesthesia is medically necessary. Our report estimated a cost of 0.05% of premium.

- ***Prosthetics*** (Enacted 2003) – This mandate requires coverage for prosthetic devices to replace an arm or leg. Our report estimated a cost of 0.03% of premium for groups over 20 and 0.08% for smaller groups and individuals.

- ***LCPCs*** (Enacted 2003) – This mandate requires coverage of licensed clinical professional counselors. Our report on mental health parity indicated to measurable cost impact for coverage of LCPCs.

These costs are summarized in the following table.

COST OF EXISTING MANDATED HEALTH INSURANCE BENEFITS

Year Enacted	Benefit	Type of Contract Affected	Est. Maximum Cost as % of Premium	
			Indemnity	HMO
1975	**Maternity** benefits provided to married women must also be provided to unmarried women.	All Contracts	0[154]	0[1]
1975	Must include benefits for **dentists'** services to the extent that the same services would be covered if performed by a physician.	All Contracts except HMOs	0.1%	--
1975	Family Coverage must cover any **children** born while coverage is in force from the moment of birth, including treatment of congenital defects.	All Contracts except HMOs	0[1]	--
1983	Benefits must be included for treatment of **alcoholism and drug dependency**.	Groups of more than 20	1.02%	0.87%
1975 1983 1995	Benefits must be included for **Mental Health Services**, including psychologists and social workers.	Groups of more than 20	5.14%	3.72%
1986 1994 1995 1997	Benefits must be included for the services of **chiropractors** to the extent that the same services would be covered by a physician. Benefits must be included for therapeutic, adjustive and manipulative services. HMOs must allow limited self referred for chiropractic benefits.	Group	1.31%	1.56%
		Individual	0.46%	0.35%
1990 1997	Benefits must be made available for screening **mammography**.	All Contracts	0.7%	0.7%
1995	Must provide coverage for **reconstruction of both breasts** to produce symmetrical appearance according to patient and physician wishes.	All Contracts	0.02%	0.02%
1995	Must provide coverage for **metabolic formula** and up to $3,000 per year for prescribed modified low-protein food products.	All Contracts	0.01%	0.01%
1996	Benefits must be provided for **maternity (length of stay)** and newborn care, in accordance with "Guidelines for Perinatal Care."	All Contracts	0	0
1996	Benefits must be provided for medically necessary equipment and supplies used to treat **diabetes** and approved self-management and education training.	All Contracts	0.2%	0.2%
1996	Benefits must be provided for **screening Pap tests**.	Group, HMOs	.01%	0
1996	Benefits must be provided for **annual gynecological exam** without prior approval of primary care physician.	Group managed care	--	0.1%
1997	Benefits provided for **breast cancer treatment** for a medically appropriate period of time determined by the physician in consultation with the patient.	All Contracts	.07%	.07%
1998	Coverage required for **off-label use of prescription drugs** for treatment of cancer, HIV, or AIDS.	All Contracts	0.3%	0.3%
1998	Coverage required for **prostrate cancer screening**.	All Contracts	.07%	0
1999	Coverage of nurse **practitioners and nurse midwives** and allows nurse practitioners to serves as primary care providers.	All Managed Care Contracts		0.16%
1999	Prescription drug must include **contraceptives.**	All Contracts	0.8%	0.8%
1999	Coverage for **registered nurse first assistants.**	All Contracts	0	0

[1] This has become a standard benefit that would be included regardless of the mandate.

2000	Access to **clinical trials.**	All Contracts	0.46%	0.46%
2000	Access to **prescription drugs.**	All Managed Care Contracts	0	0
2001	Coverage of **hospice care services** for terminally ill.	All Contracts	0	0
2001	Access to **eye care.**	Plans with participating eye care professionals	0	0.04%
2001	Coverage of **anesthesia** and facility charges for certain **dental** procedures.	All Contracts	0.05%	0.05%
2003	Coverage for **prosthetic devices** to replace an arm or leg.	Groups >20	.03%	.03%
		All other	.08%	.08%
2003	Coverage of licensed clinical professional counselors.	All Contracts	0	0
Total cost for groups larger than 20:			**10.29%**	**9.09%**
Total cost for groups of 20 or fewer:			**4.18%**	**4.55%**
Total cost for individual contracts:			**3.32%**	**3.24%**

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Appendix D: LD 213 Benefit Cost Estimates

Estimate of Impact on Premium

	Direct Costs		
	ART		
1	Incidence per 1000 women of childbearing ages for ART with fresh embryos		3.35
2	Incidence per 1000 women of childbearing ages for ART with frozen embros		0.43
3	Total Incidence		3.78
4	Cost per Cycle	$	14,260
5	% women of childbearing age represent of adult population		23%
6	Annual Cost per adult (3)/1000 x (4) x (5)	$	12.40
7	% of cycles discontinued before egg retrieval		14.2%
8	Cost per cycle	$	6,500
9	Annual cost for discontinued before egg retrieval (3)/1000 x (4) x (7) x (8)	$	0.80
10	Total annual cost per adult for ART (6) + (9)	$	13.20
	Other Infertility		
11	Percent of women of childbearing age that are infertile		13%
12	Cost to treat, including tests and procedures	$	5,000
13	% of women who will seek care in any year		12.0%
14	Annual cost per adult for Other Infertility	$	17.94
	Total Direct Costs		
15	ART	$	13.20
16	Other Infertility	$	17.94
17	Total per Adult per Year	$	31.14
18	Total cost Per Member per Year	$	24.91
19	Credit for services already paid	$	(12.00)
20	Total Cost Per Member per Year after credit	$	12.91
21	**With Retention**	$	14.67
	Retention = 12%		

Estimate of Impact on Premium

	Indirect Costs		
22	Success Rate		0.22
23	Additional Pregnancies/ 1000 Adults (3) x (5) x (22)		0.19
24	Cost of prenatal and delivery for mother	$	77,000
25	Annual cost per adults (23)/1000 x (24)	$	14.73
26	Cost per delivery (child/ren)	$	82,000
27	Annual cost of newborn care per adult (23)/1000 x (26)	$	15.68
28	Total Indirect costs per Adult per year	$	30.41
29	Total Indirect costs per Member per year	$	24.33
30	With Retention Retention = 12%	$	27.65
	All Costs		
31	Total Costs per Member per Year (21) + (30)	$	42.32
32	Estimated Insured Members in Maine		386,000
33	Premium in Maine	$	1,200,000,000
34	Total Direct Cost (21) x (32)	$	5,663,708
35	% of Premium		0.47%
36	Total Indirect Costs (30) x (32)	$	10,671,711
37	% of Premium		0.89%
38	Total All Costs (30) + (36)	$	16,335,419
39	% of Premium		1.36%

The number of insured in Maine is estimated by dividing the members for Anthem (220,554) by it market share 57%

Appendix E: Glossary

Glossary[55]

Abortion: Termination (either spontaneous or induced) of a clinical pregnancy before 20 weeks gestation.

Artificial Insemination (AI): Placing sperm into the vagina, uterus or fallopian tubes through artificial means instead of by coitus -- usually injected through a catheter or cannula after being washed. This procedure is used for both donor (AID) and husband's (AIH) sperm. This technique is used to overcome sexual performance problems, to circumvent sperm-mucus interaction problems, to maximize the potential for poor semen, and for using donor sperm.

Assisted Reproductive Technologies (ART): Technologies that manipulate the eggs and sperm outside of the woman's body, with the aim of establishing a healthy pregnancy. The most common procedure is IVF.

Biochemical pregnancy: A pregnancy that is diagnosed by a hormonal assay for human chorionic gonadotropin. Convention requires a level above 100 mIU/ml or rising levels two or more days apart.

Clinical pregnancy: A pregnancy that could be diagnosed clinically. This has come to the defined as a pregnancy in which a gestational sac can be identified by ultrasound.

Commenced cycle: A proposed treatment cycle in which the patient has begun taking medication.

Completed cycle: A treatment cycle in which the patient completed all planned portions of the cycle including transfer of embryos (or gametes for a GIFT procedure).

Confidence interval: An interval defined with a percentage (usually 95%) in which the stated percentage of expected observations would fall, given multiple trials under the same conditions.

Delivery: The delivery of a baby past 20 weeks gestation.

Ectopic pregnancy: A pregnancy that has begun to grow outside the uterine cavity, usually in the fallopian tube.

Embryo transfer: The procedure used to transfer the embryos back to the patient, usually done transcervically into the uterus. It is occasionally done, under laparoscopic visualization, into the fallopian tube.

[55] The Glossary was provided by Dr. Peter M. Martin and the InterNational Council on Infertility Information

Endometrial Biopsy (EB, Ebx, EMB): A test to check for Luteal Phase Defect or Hyperplasia. A procedure during which a sample of the uterine lining is collected for microscopic analysis. The biopsy results will confirm ovulation and the proper preparation of the endometrium by estrogen and progesterone stimulation.

Follicular stimulating hormone, (FSH): The hormone produced by the pituitary gland that stimulates ovarian follicular growth, with its associated oocyte. FSH is one of two gonadotropins produced by the pituitary gland.

Gamete: A reproductive cell, e.g., a sperm or an oocyte

Gamete intrafallopian tube transfer (GIFT): A technique that may be used in lieu of in vitro fertilization for women with patent (clear and open) tubes. After egg retrieval the eggs are mixed with sperm and then immediately injected through the fimbria into the woman's fallopian tubes for in vivo fertilization. Procedure is done through laparoscopy.

High order multiple pregnancy (HOM): A multiple pregnancy in which three or more gestational sacs are identified by ultrasound.

Hyperstimulation (Ovarian Hyperstimulation Syndrome, OHSS): A potentially life-threatening side effect of ovulation induction with injectable fertility medications such as hMG and urofollitropins. A woman's ovaries become enlarged and produce an overabundance of eggs. Blood hormone levels rise, fluid may collect in the lungs or abdominal cavity, and ovarian cyst may rupture, causing internal bleeding. Blood clots sometimes develop. Symptoms include sudden weight gain and abdominal pain. Cycles stimulated with these drugs must be carefully monitored with ultrasound scans. OHSS may be prevented by withholding the hCG injection when ultrasound monitoring indicates that too many follicles have matured.

Hysterosalpinogram (HSG): An x-ray of the pelvic organs in which a radio-opaque dye is injected through the cervix into the uterus and fallopian tubes. This test checks for malformations of the uterus and blockage of the fallopian tubes.

Hysteroscopy (HSC): A procedure in which the doctor checks for uterine abnormalities by inserting a fiber-optic device. Minor surgical repairs can be executed during the procedure.

Intracyctoplasmic sperm injection (ICSI): A micromanipulation procedure in which an individual sperm is injected directly into the cyctoplasm of an individual oocyte.

Implantation: The condition in which an embryo has attached (usually to the endometrial lining of the uterine cavity) and begun to grow.

In vitro fertilization (IVF): The process of fertilization occurring in the laboratory. Literally means "in glass." Fertilization takes place outside the body in a small glass dish.

Laparoscope: A small telescope that can be inserted into a hole in the abdominal wall for viewing the internal organs; the instrument used to perform a laparoscopy. Used to diagnose and treat a number of fertility problems including endometriosis, abdominal adhesions, and polycystic ovaries. Also used in egg retrieval for in vitro fertilization. Examination of the pelvic region by using a laparoscope is called a laparoscopy.

Luteinizing hormone (LH): The hormone produced by the pituitary gland, released in a surge pattern over 24 hours, that induces the final maturation of the oocyte and ovulation, 24 to 36 hours after the production of the surge.

Live born: A baby past 20 weeks gestation that is alive when born.

Mean: The arithmetic average of series of values defined as the sum divided by the number of observations.

Miscarriage: A nonmedical term for a clinical spontaneous abortion.

Multiple pregnancy: A pregnancy in which more than 1 embryo has implanted and begun to grow.

Ovary: The female gonad, which produces oocytes and hormones to support a pregnancy.

Ovulation: The process of the ovary releasing an oocyte.

Ovulation induction: Stimulating the ovary to mature and release a mature oocyte. This can be for a single oocyte for a patient who does not ovulate, or for multiple oocytes to try to increase the chances of a pregnancy with insemination or for ART procedures.

Ovum: The egg; the reproductive cell from the ovary; the female gamete; the sex cell that contains the woman's genetic information.

Oocyte retrieval: The procedure, usually done under vaginal ultrasound guidance, to retrieve oocytes to be used for GIFT or IVF.

Oocyte: Female gamete (egg).

P-value: The probability of obtaining a mean as extreme or more extreme than the observed value, as compared with the reference value.

Sonogram (Ultrasound): Use of high-frequency sound waves for creating an image of internal body parts. Used to detect and count follicle growth (and disappearance) in many fertility treatments. Also used to detect and monitor pregnancy.

Sperm: Male gamete.

Standard deviation: A measure of the dispersion of values about the mean of a number of

observations. In a normally distributed set of observations approximately 67% of the values fall within a range plus or minus one standard deviation of the mean.

Testicle: The male gonad, which produces sperm and male hormones.

Tubal embryo transfer (TET): Usually done under laparoscopic visualization. The placement of an embryo inside the fallopian tube after in vitro fertilization. The process is meant to mimic the natural process of a fertilized embryo traveling down the tube and implanting in the uterus.

Zygote: A fertilized egg, before cell division starts.

Zygote intrafallopian tube transfer (ZIFT): Usually done under laparoscopic visualization. An ART in which eggs are removed from a woman's ovaries, fertilized with the man's sperm in a lab dish, and the resulting Zygotes are transferred into the woman's fallopian tubes during a minor surgical procedure.

Appendix F

Treatment of Male Infertility[56]

In recent years there has been a great increase in scientific and medical interest in male infertility and the range of treatment options currently available includes drug therapy, surgery and ART. The main approaches to the treatment of male infertility are described below.

- Drug Therapy
- Surgical Therapy
- ART in Male Infertility
- Intracytoplasmic Sperm Injection (ICSI)

Drug Therapy

Fewer than 5% of infertile men have a hormonal disorder that can be treated with hormone therapy. Hormonal imbalances caused by a dysfunction in the mechanism of interaction between the hypothalamus, the pituitary gland and the testes directly affect the development of sperm. In this type of fertility disorder, FSH therapy is highly successful. Gonadotropins are sometimes chosen to treat unexplained male infertility, as seen in the cases of oligozoospermia (when sperm count is abnormally low) or asthenospermia (when less than 40% of the sperm are motile). Other types of drug treatment include antibiotics to treat infertility resulting from infections and treatment with bromocriptine when impaired sperm production is due to hyperprolactinaemia (increased levels of prolactin hormone in the blood).

Surgical Therapy

Surgical therapy in male infertility aims at overcoming anatomical barriers impeding sperm production and maturation (in the testes and the epididymis) or ejaculation. Several techniques have been developed, whereby spermatozoa are retrieved either from the epididymis (percutaneous epididymal sperm aspiration, PESA, or microsurgical epididymal sperm aspiration, MESA) or from the testes (testicular sperm aspiration, TESA or testicular sperm extraction, TESE). These techniques are mainly used in conjunction with ICSI.

[56] Pepe, Pamela of Serono, in communication with the Maine Bureau of Insurance. Referenced original source as the World Wide Fertility Network, www.Ferti.Net

ART in Male Infertility

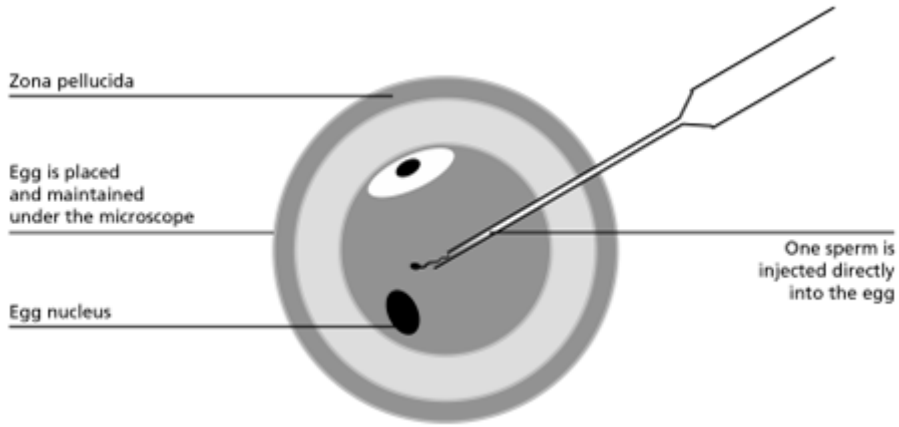
Some of the ART procedures described as treatment for female infertility are relevant to certain types of male infertility. See Intravaginal Insemination and *In Vitro* Fertilization.

Intracytoplasmic Sperm Injection (ICSI)

Intracytoplasmic sperm injection is a m*icromanipulation* technique in which fertilization is brought about by the injection of a single spermatozoon into an unfertilized egg (or oocyte, - see illustration 2). ICSI is performed with eggs obtained after ovulation stimulation as for IVF, and has greatly improved the treatment of male infertility as a result of severe oligozoospermia (abnormally low sperm count).

ICSI requires only one spermatozoon for each egg and because of this, its indications have been expanded to include nearly all men with serious infertility, including many who would previously have been considered hopeless cases. Provided the spermatozoa are viable, even sperm dysfunction may be overcome, since more than 50% of eggs fertilize normally regardless of the sperm quality. Obstructive azoospermia (absence of sperm in the ejaculate) can also be treated by retrieval of spermatozoa directly from the testes and even immature spermatozoa have been used to produce embryos.

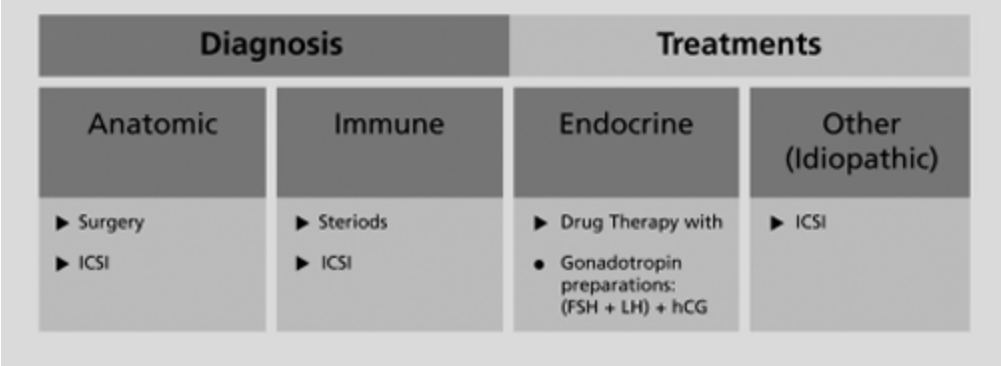
Illustration 2: Intracytoplasmic sperm injection (ICSI)



The success rates in ICSI are greatly influenced by the quality of sperm preparation and by the skill of micromanipulation. ICSI, combined with IVF, is the most effective treatment for male infertility with a success rate of 20-25% of treatments resulting in a live birth.

Summary

Table 3: Main approaches to the treatment of male infertility



Diagnosis		Treatments	
Anatomic	Immune	Endocrine	Other (Idiopathic)
▶ Surgery ▶ ICSI	▶ Steriods ▶ ICSI	▶ Drug Therapy with • Gonadotropin preparations: (FSH + LH) + hCG	▶ ICSI

Treatment of Female Infertility

Several options for treatment are offered to patients depending on the type of infertility diagnosed. The vast majority of female patients are successfully treated with the administration of drugs such as clomiphene citrate, gonadotropins or bromocriptine. Surgery can also be a means to repair damage to the reproductive organs such as those caused by endometriosis and infectious diseases. The main approaches to the treatment of female infertility are outlined here and described below.

- Ovulation Induction (OI)
- Assisted Reproductive Technologies (ART)
- Intrauterine Insemination (IUI)
- Intravaginal Insemination (IVI)
- In-vitro Fertilization (IVF)*
- Gamete Intrafallopian Transfer (GIFT)*
- Zygote Intrafallopian Transfer (ZIFT)*

*Note: of these three ART procedures, IVF is likely to be performed 96% of the time, with GIFT and ZIFT comprising the remaining 4%. However, very few infertility patients ever access any of these three treatments, having achieved conception success much earlier in their treatment regimen.

Summary – Art at a Glance

ART PROCEDURES

Procedure	Description	Indications	Remarks
Artificial insemination	• Large numbers of healthy sperm are injected at the entrance of the cervix or high in the uterus, bypassing the cervix and giving direct access to the fallopian tubes • Prior to injection, sperm is specially prepared in the laboratory to maximize its fertilizing ability	• Existence of sperm antibodies in a woman's cervical mucus • Male infertility due to low sperm count or low number of healthy sperm (see also ICSI) • Other sperm abnormalities which prevent fertilization (see also ICSI)	• A minimum of viable sperm needs to be available - chances of success decrease if sperm count is low or if only a few spermatozoa are motile
IVF (In Vitro Fertilization)	• Hormone therapy with gonadotropins is given to stimulate the ovaries to produce several mature eggs • Eggs are retrieved and fertilized *in vitro* with either the partner's or donor sperm • If fertilization occurs within 24 to 28 hours, one or more embryo(s) are placed in the uterus	• Treatment of infertility due to fallopian tube occlusion and endometriosis • Male infertility due to sperm abnormalities which prevent fertilization • Some cases of unexplained infertility	• As fertilization occurs *in vitro*, IVF used in male infertility can serve to detect specific sperm abnormalities, such as the inability of seemingly good quality sperm to fertilize
GIFT (Gamete Intra-Fallopian Transfer)	• Follows same procedures as IVF except that fertilization occurs in the body (*in vivo*) • Spermatozoa and eggs are placed directly into the fallopian tubes where fertilization can occur	• Infertility due to endometriosis and cervical mucus disorders • Unexplained infertility • Some cases of male infertility	• Can only be practiced if fallopian tubes are healthy • There is no way to verify that fertilization has taken place, since it occurs *in vivo*
ZIFT (Zygote Intra-Fallopian Transfer)	• Same procedures as IVF except that fertilized eggs are placed in the fallopian tubes at a certain stage of embryo development (zygote)	• Same as for GIFT	• Can only be practiced if fallopian tubes are healthy
ICSI (Intracytoplasmic Sperm Injection)	• An *in vitro* microsurgical fertilization technique in which a single sperm is selected and injected into an egg • Performed with eggs obtained after ovulation stimulation as done in IVF	• Male infertility when very few normal sperm are available **and/or** • Fertilizing ability of sperm is dramatically reduced	• Has become an alternative to artificial insemination with donor sperm
MESA (Microsurgical Epididymal Sperm Aspiration)	• Spermatozoa are retrieved directly from the epididymis (area in the testes where spermatozoa mature and are stored) • Fertilization is then attempted with ICSI	• Severe male infertility • Absence of sperm in the ejaculate (azoospermia) • Congenital abnormalities (e.g. absence of vas deferens)	• Usually enough sperm can be retrieved from one procedure to be frozen for later use if required

TESE (Testicular Sperm Extraction)	• Biopsy of the testes is performed in order to obtain spermatozoa directly from testicular tissue • Fertilization is then attempted with ICSI	• Severe male infertility • Absence of sperm in epididymis • Absence of epididymis	• Option if MESA is not possible